Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of family presence on pain and pain anxiety dressing of patient in burn intensive care unit in zare hospital

Protocol summary

Summary

The aim of this Randomized Clinical Trial is to determine the effect of family attendance on pain and anxiety arising from the pain of dressing change of patients from intensive care ward in ZARE HOSPITAL of SARI.Inclusion Criteria: All patients over 18 years old, alert, burn more than 10% Grade 2 and 3 with moderate and severe burns.Exclusion Criteria: Drug Addiction, A History of Severe Mental Illness, Mental Retardation and Cognitive, Respiratory Distress, Intubated, Infection of the Wound, Transfer, Discharge and Death. Sample: 110 Patients are in two groups each (n = 55) based on random assignment experimental and control groups. On third day of admission, participants (preferably relative) in the event of dont having severe anxiety entered in the study. Then, training includes the patient's condition, the provisions of section, treatment of patients with wound dehiscence, infection control precautions including hand washing, entry requirements and duration of the clinical evaluation of the patient's manipulation of joints, participation in nutrition as primary care offered by the researcher. In the intervention group, from fourth day of hospitalization, a family member for 5 consecutive days in one-hour meetings and before dressing will be present at bedside of the patient. Control group (without mobile) will be treated. Anxiety and pain caused by burns after pain and 15 minutes before dressing, and intensity immediately before and after dressing for 6 consecutive days (3rd to 8th days) in the two groups will be discussed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602297494N17**
Registration date: **2016-05-18, 1395/02/29**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-05-18, 1395/02/29

Registrant information

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Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2016-03-05, 1394/12/15

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of family presence on pain and pain anxiety dressing of patient in burn intensive care unit in zare hospital

Public title

The effects of family presence on pain and pain anxiety dressing of patient in burn intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: All patients over 18 years old, alert, burn more than 10% Grade 2 and 3 with moderate and severe burns.Exclusion Criteria: Drug Addiction, A History of Severe Mental Illness, Mental Retardation and Cognitive, Respiratory Distress, Intubated, Infection of the Wound, Transfer, Discharge and Death.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Start of valiye asr highway, Imam Square, Sari, Mazandaran

City

sari

Postal code

4736131167

Approval date

2016-02-21, 1394/12/02

Ethics committee reference number

IR.MAZUMS.REC.94-2126

Health conditions studied

1

Description of health condition studied

Burns and corrosions

ICD-10 code

T20-T32

ICD-10 code description

Burns and corrosions

Primary outcomes

1

Description

Burn pain anxiety

Timepoint

15 minutes before dressing change from the third to the eighth hospitalization day

Method of measurement

Burn specific Pain Anxiety Scale

2

Description

Pain

Timepoint

Immediately before and after dressing change from the third to the eighth hospitalization day

Method of measurement

Visual Analog scale

Secondary outcomes

empty

Intervention groups

1

Description

The one-hour-presence of the patient's desired attendant at bedside for five consecutive days before dressing by observing train cases from 4th to 8th hospitalization day.

Category

Other

2

Description

The absence of attendant in a control group with will perform.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Hospital

Full name of responsible person

Masoomeh Koohi

Street address

Zare Hospital,sari

City

Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research Mazandaran University of Medical Sciences.
Full name of responsible person
Dr.Ahmadali Enayati
Street address
Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran.
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research Mazandaran University of Medical Sciences.
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty